

**United States Government Accountability Office** 

Report to the Ranking Member, Committee on Veterans' Affairs, House of Representatives

January 2020

# VA HEALTH CARE

Efforts to Prioritize and Translate Research into Clinical Practice

# GAO Highlights

Highlights of GAO-20-211, a report to the Ranking Member of the Committee on Veterans' Affairs, House of Representatives

#### Why GAO Did This Study

In addition to providing health care services, VA funds research on veterans' health conditions, including chronic conditions (such as diabetes) as well as illnesses and injuries resulting from military service (such as TBI). VA's ORD manages the agency's research program, including its intramural research. In fiscal year 2018, VA resources for its intramural research program included an appropriation of \$722 million.

GAO was asked to review aspects of VA's research program. In this report, which focuses on VA's intramural research, GAO describes 1) how VA sets priorities for funding research, 2) VA efforts to facilitate translation of research into clinical practice, and 3) coordination between VA's research program and other VA entities.

To perform this work, GAO reviewed VA policies, reports, and other documents about VA research efforts. GAO also interviewed officials from ORD, three VA national clinical program offices, and two VA offices that focus on implementing evidence-based practices. In addition, GAO conducted site visits with four VA medical centers. GAO selected those locations because they house VA-funded research centers that focus on a range of topics and ORD programs that focus on disseminating and translating research. At each location, GAO interviewed medical center officials and VA researchers. GAO also reviewed VA summary data on research projects and funding for fiscal year 2018.

VA provided technical comments on a draft of this report, which GAO incorporated as appropriate.

View GAO-20-211. For more information, contact Jessica Farb at (202) 512-7114 or farbj@gao.gov.

### VA HEALTH CARE

# Efforts to Prioritize and Translate Research into Clinical Practice

#### What GAO Found

The Department of Veterans Affairs (VA) uses stakeholder input and other information to set priorities for funding research projects. VA's Office of Research and Development (ORD) manages VA's intramural research program—that is, research funded by and conducted within VA, by VA researchers. To set priorities, ORD considers input from VA and non-VA stakeholders (such as agency leaders and a federal research advisory council, respectively) and data on veterans' health conditions. ORD encourages VA researchers to study—and collaborate with other VA researchers on—priority topics, such as post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI).

Examples of Veterans Affairs (VA) Intramural Research Projects on Priority Topics

#### PTSD and TBI

Studies on the long-term effects of post-traumatic stress disorder (PTSD) and mild traumatic brain injury (TBI), and a program to help veterans who served in Iraq or Afghanistan strengthen behavioral and emotional skills.

#### Spinal cord injury

Studies on using exoskeletons—motorized prostheses worn outside a person's clothes to help veterans walk in rehabilitation, home, and community settings; improving arm, leg, and bowel function; and addressing low blood pressure.



VA research participant with a spinal cord injury uses an exoskeleton.

Source: VA (information and photo). | GAO-20-211

ORD's Quality Enhancement Research Initiative (QUERI) and other VA entities facilitate translating research findings into clinical practice to improve care for veterans. QUERI is VA's central point of focus for research translation and provides a link between ORD, VA program offices, and providers. For example, one QUERI program is studying delivery of an evidence-based treatment for PTSD using telemedicine, specifically, by providing psychotherapy via video to veterans in rural areas. Another program recently adopted a new research translation strategy by establishing a requirement that research proposals for large, multi-center clinical trials include an implementation plan. VA officials said the goal of the new requirement is to encourage researchers to think about research translation from the beginning of a study—and how their work might be translated into practice.

VA officials from both ORD and the national program offices GAO spoke with described a variety of efforts coordinating on research. Such coordination can help inform research priorities and help program offices incorporate evidencebased practices in developing and rolling out national policies. For example, ORD officials said that VA researchers were serving as subject matter experts to the national program office developing a protocol and clinical guidelines for a new treatment for certain veterans with depression that is resistant to existing treatments.

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Priorities, Fiscal Years (FY) 2019 and 2020

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#### Abbreviations

| COIN<br>DOD<br>NIH<br>ORD<br>PTSD<br>QUERI<br>TBI<br>VA<br>VBA | Center of Innovation<br>Department of Defense<br>National Institutes of Health<br>Office of Research and Development<br>post-traumatic stress disorder<br>Quality Enhancement Research Initiative<br>traumatic brain injury<br>Department of Veterans Affairs<br>Veterans Benefits Administration |
|--|---|
| VBA  | •   |
| VHA  | Veterans Health Administration  |
| VISN   | Veterans Integrated Service Network   |
|  |   |

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W. Washington, DC 20548

January 23, 2020

The Honorable David P. Roe, M.D. Ranking Member Committee on Veterans' Affairs House of Representatives

Dear Dr. Roe:

In addition to providing care to more than 9 million veterans through the nation's largest integrated health care system, the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) funds research focused on health conditions veterans may experience. According to VA, the department's research program has led to health care breakthroughs that have improved the lives of veterans and the public for more than 90 years.<sup>1</sup> The department's research has been instrumental in medical advances such as therapies for tuberculosis following World War II, the implantable cardiac pacemaker, the first successful liver transplants, and the first powered ankle-foot prosthesis.

VA funds studies on a variety of topics through its intramural research program—research that is funded by and conducted within VA by VA investigators. This research has included genomic and tissue studies done in laboratories; studies of suicide prevention efforts; and studies of rehabilitation engineering, prosthetics, and orthotics.<sup>2</sup> In general, these studies can address veterans' everyday health care needs as well as the

<sup>&</sup>lt;sup>1</sup>VA's research program is authorized in statute, specifically for the purpose of more effectively carrying out "the primary function of the Administration and in order to contribute to the Nation's knowledge about disease and disability." The research conducted by the program is to be done in connection with the provision of medical care and treatment to veterans. 38 U.S.C. § 7303.

<sup>&</sup>lt;sup>2</sup>The term "prosthetics" refers to any device that supports or replaces a body part or function, such as a hearing implant or prosthetic limb. The term "orthotics" refers to a device fitted externally to an anatomical portion of the body to influence motion by assisting, resisting, blocking, or unloading part of the body weight.

particular needs of veterans with illnesses and injuries resulting from their military service.<sup>3</sup>

VHA's Office of Research and Development (ORD) manages VA's intramural research program. In fiscal year 2018, VA's intramural research program received an appropriation of \$722 million.<sup>4</sup> VA also participates in extramural research, which is funded through other federal and non-federal sources.<sup>5</sup>

To support its mission of advancing health care for veterans and the nation, ORD policy states that its research program should focus on supporting research to increase the evidence base for treatments and disseminating research results to put those results to use. The process of "translating" research findings into clinical practice—also known as "implementation"—can occur in many ways within VA. For example, research translation can result in changes to direct patient care (e.g., introducing a new diagnostic tool or directing providers to follow a new treatment protocol), or it can involve broader changes to VA programs (e.g., implementing a new staffing policy for a particular provider type). ORD works with other entities within the agency—including those that set clinical policies—in research translation. Research translation is widely accepted to be a long process; for example, one study reported that on average, it takes 17 years for research evidence to reach clinical practice.<sup>6</sup> Numerous factors, such as limited resources and time for providers to implement evidence-based practices in delivering clinical care, can prolong the process of research translation.

<sup>&</sup>lt;sup>3</sup>The law authorizing VA's research program provides that it is to include biomedical research, mental illness research, prosthetic and other rehabilitative research, and health-care-services research and is to stress research into spinal-cord injuries and other diseases that lead to paralysis of the lower extremities, and research into injuries and illnesses particularly related to service. 38 U.S.C. § 7303(a).

<sup>&</sup>lt;sup>4</sup>VA also supports its intramural research program through other VA appropriations and reimbursements.

<sup>&</sup>lt;sup>5</sup>Extramural research at VA is administered through VA academic affiliates or nonprofit research and education corporations. We are also conducting a review of VA's extramural research to be issued in a subsequent report.

<sup>&</sup>lt;sup>6</sup>Z.S. Morris, S. Wooding, and J. Grant, "The Answer is 17 Years, What is the Question: Understanding Time Lags in Translational Research," *Journal of the Royal Society of Medicine*, 104 (2011): p. 510-520.

Congress and others have previously raised questions about the extent to which VA's research program is fulfilling its intended purpose in conducting research focused on veterans' needs.<sup>7</sup> You asked us to review several aspects of VA's research program. This report focuses on VA's intramural research program and describes

- (1) how VA sets priorities for funding research projects;
- (2) VA efforts to facilitate translation of research findings into clinical practice; and
- (3) coordination between VA's research program and other relevant parts of the agency on setting research priorities and translating research into clinical practice.

For all three objectives, we reviewed relevant statutes as well as VA policies, reports, and other documents about agency research efforts. We reviewed, for example, VA directives that govern the intramural research program and VA's budget submission for fiscal year 2020. We also interviewed ORD officials, including the Chief Research and Development Officer and the directors of ORD's four research services—offices within ORD responsible for administering and supporting different types of research efforts. In addition, we conducted site visits with four VA medical centers that house ORD-funded research centers and other ORD programs.<sup>8</sup> We selected those sites based on their research centers' and programs' areas of focus. Specifically, we selected sites with research centers that focus on different clinical and research areas and with other ORD programs that focus on disseminating research and translating

<sup>&</sup>lt;sup>7</sup>Additionally, we and others have cited longstanding concerns about VA's oversight of its health care system. These concerns contributed to veterans' health care being placed on GAO's High-Risk List beginning in 2015. GAO maintains a high-risk list to focus attention on government agencies and programs that it identifies as high risk due to their greater vulnerabilities to fraud, waste, abuse, and mismanagement or the need for transformation to address economy, efficiency, or effectiveness challenges. We have identified five areas of concern for VA health care: (1) ambiguous policies and inconsistent processes; (2) inadequate oversight and accountability; (3) information technology challenges; (4) inadequate training for VA staff; and (5) unclear resource needs and allocation priorities. GAO, *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP (Washington, D.C.: Mar. 6, 2019).

<sup>&</sup>lt;sup>8</sup>The medical centers we selected are located in Ann Arbor, Mich.; Boston, Mass.; Bronx, N.Y.; and Seattle, Wash.

research into clinical practice.<sup>9</sup> (See appendix I for these research centers and programs.) At each site, we interviewed VA medical center officials and researchers about VA's research efforts and their local VA-funded research projects. The information obtained during those site visits is not generalizable. For context, we also reviewed VA data on research projects and funding for fiscal year 2018.

To describe how VA sets priorities for funding research projects, we reviewed documents such as VA requests for applications, which describe the types of projects for which VA researchers may apply for funding. We also interviewed ORD officials about how they set research priorities, their current priorities, and how they incorporated those priorities into their processes for funding research projects.

To describe VA efforts to facilitate translation of research findings into clinical practice, we interviewed ORD and other VA officials who focus on implementing evidence-based practices in VA. This included officials from ORD's Quality Enhancement Research Initiative (QUERI) program, which works to translate research findings and evidence-based treatments into clinical practice, as well as VA's Diffusion of Excellence Office and Evidence-Based Practice Program Office.<sup>10</sup> We also reviewed VA documentation of agency efforts to translate research findings, documentation of VA research projects that led to changes in clinical practice, and other documents related to research translation, such as publications in academic journals. We focused our review on research translation efforts pertaining to ORD's intramural research program.

To describe coordination between VA's research program and other relevant parts of the agency on setting research priorities and translating research into clinical practice, we interviewed officials from three VA national program offices—the Office of Mental Health and Suicide Prevention, Office of Rehabilitation and Prosthetics Services, and Office

<sup>9</sup>ORD funds 30 VA medical center-based research centers that focus on specific research topics; we included six of those centers in this review. ORD also operates more than 40 VA medical center-based programs that focus on translating research into clinical practice; we included six of those programs in this review. We also included an ORD program that focuses on disseminating information related to VA research.

<sup>10</sup>VA's Diffusion of Excellence office, which is outside of ORD, encourages implementation of research-based practices. The Evidence-Based Practice Program Office, also outside of ORD, works to ensure that health care is standardized and based in scientific research across both VA and the Department of Defense (DOD), primarily through the development of clinical practice guidelines.

of Spinal Cord Injuries and Disorders System of Care—about their related efforts.<sup>11</sup> We selected these offices because the clinical areas in their purview are relevant to VA research centers and programs we visited and to VA's research priorities at the time of our review. The information obtained from those program offices is not generalizable to the efforts of other program offices. We also reviewed documentation of research efforts in which VA research program and national program office staff had collaborated.

We conducted this performance audit from October 2018 to January 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

VA, through VHA, operates the nation's largest integrated health care system. At the local level, VA has 172 VA medical centers that are organized into 18 Veterans Integrated Service Networks (VISN).<sup>12</sup> At the national level, VHA's central office includes approximately 75 national program offices as of October 2019, which perform a range of clinical or administrative functions. For example, some program offices are responsible for specific clinical areas, such as spinal cord injury or mental health care, and may develop policy for those areas.

To support VA's health care delivery system, VA's intramural research program aims to improve veterans' health by funding research on issues that affect veterans, developing effective treatments for veterans, and recruiting and retaining VA researchers. VA's medical and prosthetic research appropriation—\$722 million in fiscal year 2018—funds VA's

<sup>&</sup>lt;sup>11</sup>These three national program offices play a role in developing policy and monitoring the provision of health care services within their specific clinical areas.

<sup>&</sup>lt;sup>12</sup>VISNs are responsible for overseeing VA medical centers within a defined geographic area. VA medical centers manage outpatient facilities located within their respective medical centers; these outpatient facilities include more than 1,000 community-based outpatient clinics and health care centers.

intramural research program.<sup>13</sup> VA also uses funding from its other appropriation accounts—\$544 million in fiscal year 2018—to support VA's intramural research by paying some costs associated with this research, such as equipment maintenance. According to VA, more than 60 percent of VA researchers are also clinicians who provide direct patient care, which helps translate VA research into clinical practice.

ORD manages VA's intramural research program. Within ORD, there are four research and development services that are responsible for administering and supporting research; each research service has a specific focus, such as biomedical research and rehabilitation research. Each of the four research services is led by a director and has scientific program managers who are responsible for specific research portfolios (or topic areas) within their service. In addition to the four research services, ORD has a Cooperative Studies Program that is responsible for large-scale clinical trials and epidemiological studies within VA. (See Table 1.) All five of these ORD components support research by funding VA research projects.<sup>14</sup> See appendix II for details on research funding and awards. Organizationally, ORD falls within the Office of Discovery, Education and Affiliates Networks, which was created in November 2018 to foster collaboration in addressing veterans' health concerns.<sup>15</sup>

<sup>&</sup>lt;sup>13</sup>VA's medical and prosthetic research appropriation pays for necessary expenses in carrying out programs of medical and prosthetic research and development as authorized by chapter 73 of title 38, United States Code, the authorizing laws for the Veterans Health Administration. See Pub. L. No. 115-141, 132 Stat. 348, 809 (2018).

<sup>&</sup>lt;sup>14</sup>In addition to these components, ORD has offices focusing on areas such as technology transfer (e.g. patenting and licensing); the Million Veteran Program, which provides the infrastructure for enrolling at least 1 million veterans to create a research database of genetic, health, lifestyle, and military exposure information; human subject protection; and information technology. In addition to ORD's intramural research program—the focus of this report—VA also has other non-ORD programs and centers that conduct or support research. For example, the National Center for PTSD is part of the Office of Mental Health and Suicide Prevention and focuses on PTSD research.

<sup>&</sup>lt;sup>15</sup>VA's Office of Academic Affiliations and its Innovation Ecosystem are also part of this new office.

#### Table 1: Office of Research and Development's (ORD) Intramural Research Services and Cooperative Studies Program

| ORD component  | Focus of research  | Examples of research   |
|--|--|--|
| Biomedical Laboratory Research & Development Service | Understanding life processes and diseases from the molecular, genomic, and physiological level.  | Research on animal models and investigations of tissues,<br>blood, or other biologic specimens from humans. Research<br>topics include post-traumatic stress disorder (PTSD), blast<br>injury, and cancer, among others.                               |
| Clinical Science Research & Development Service      | Moving ideas along the pathway from<br>scientific discovery to clinical<br>application, with human beings as the<br>unit of study and a focus on clinical<br>trials. | studies. Research topics include post-deployment mental  |
| Health Services Research & Development Service       | The organization, delivery, and<br>financing of health care, from the<br>perspectives of patients, caregivers,<br>providers, and managers.                           | Studies on quality, effectiveness, efficiency, cost, and accessibility of health services. Research topics include complex chronic diseases, mental health, opioid use, and women's health, among others.  |
| Rehabilitation Research & Development Service        | Studies of advanced treatments<br>designed to maximize recovery and<br>minimize the long-term<br>consequences of disabling<br>conditions.                            | Pre-clinical, clinical, and development studies, through<br>evaluation and technology transfer to final clinical<br>application. Research topics include prosthetic devices,<br>traumatic brain injury, spinal cord injury, and pain, among<br>others. |
| Cooperative Studies Program                          | Large multicenter clinical trials and epidemiological studies.   | Studies that assess the effectiveness of health care<br>practices such as medication, surgery, and psychotherapy.<br>Research topics include mental health, such as PTSD;<br>cancer; heart disease; and pulmonary health, among<br>others.             |

Source: GAO summary of information from VA | GAO-20-211

Note: In addition to funding research projects, some of ORD's components also have centers that support VA research efforts. For example, the Health Services Research & Development Service has resource centers that provide support for VA research in several areas, including data, health economics, and dissemination.

ORD funds VA intramural research in a number of ways, such as the following:

• Merit Review Program. This program supports VA research projects that are typically led by one VA researcher at one VA facility. ORD's four research services administer this program and are responsible for soliciting, reviewing, selecting, and funding research proposals submitted by VA researchers. Researchers may submit proposals either in response to a request for applications on a specific topic (sometimes called targeted or focused requests) or to a general request for applications, for which researchers can propose projects on a wider range on topics. To be considered for funding, research

proposals must be veteran-centric and meet other requirements.<sup>16</sup> Each ORD research service typically evaluates Merit Review Program research proposals in two review cycles per year. Selected projects are funded for a set number of years and have a maximum budget typically for four years with a maximum amount of \$1.2 million. The Merit Review Program accounts for the majority of VA-funded research studies that ORD funds.<sup>17</sup>

- Cooperative Studies Program. This program funds larger-scale, multi-site clinical trials and epidemiological research studies on diseases that affect veterans.<sup>18</sup> VA researchers can submit proposals at any time during the year. ORD's Chief Research and Development Officer and Cooperative Studies Program leadership evaluate proposals in two review cycles per year. The time frame and budget for selected studies varies, depending on features of specific studies.
- **Career Development Program awards.** The research services' Career Development Program provides funding to support, train and mentor individuals early in their career as VA researchers, which can include funding for specific research projects.
- Funding to support VA research centers and entities. In addition to funding individual research projects and researchers, ORD funds research centers and entities that focus on specific research areas. For example, the rehabilitation research service provides "core funding" to support 12 research centers focusing on areas such as limb loss, spinal cord injury, vision loss, and auditory disorders. This type of funding is competitive, and VA researchers must recompete in 5-year cycles.

Once research has been completed, the findings can inform additional research. For example, research findings from a study on tissue could be used to inform a study done on humans in a controlled clinical setting, such as a clinical trial, which could in turn inform research that tests the effectiveness of a particular intervention in a less-controlled community

<sup>16</sup>For example, the principal investigator and any co-principal investigators must demonstrate a primary professional commitment to VA, including at least a 5/8-time VA appointment at the time the funding is awarded.

<sup>17</sup>Research services also may fund shorter-term pilot or exploratory studies to determine if additional research in an area should be conducted. Combined, merit review and pilot studies accounted for 97 percent of studies funded in fiscal year 2018.

<sup>18</sup>The Cooperative Studies Program accounted for 2 percent of VA-funded research studies, but 17 percent of award funding in fiscal year 2018.

setting. This concept is referred to as the "research pipeline." Research findings leading to broad changes in clinical practice that affect public health is considered the end of the pipeline.

Within VA, research findings can be translated into clinical practice in a number of ways, such as by implementing a new diagnostic tool, changing the treatment protocol for a particular disease, adding a new prompt for providers in the electronic health record, or developing a new clinical policy or a clinical practice guideline.<sup>19</sup> The specific outcome might vary depending on the study or type of research. For example, one body of VA research has confirmed the utility of an intimate partner violence screening tool for female veterans in primary care settings. These findings will be used in developing national guidelines for screening for, and responding to, intimate partner violence. In addition, VA research contributed to the development of a clinical practice guideline for the management of upper extremity amputation rehabilitation. This guideline is a tool to assist clinicians and health care professionals with their decision-making when caring for individuals with upper extremity amputation.

VA Uses Stakeholder Input and Other Factors to Set Priorities for Funding Research Projects ORD leadership sets VA's national research priorities based on input from internal and external stakeholders and other factors. The directors of ORD's four research services, in turn, set their own service-level research priorities based on the national priorities, veterans' specific needs, and other considerations. Once these research priorities are set, ORD officials use a range of approaches to incorporate them when funding research, such as by funding collaborative research efforts focused on specific priorities. ORD officials said in funding research, they also consider other clinical and research needs that are not identified as priorities but are still important to veterans' health, such as encouraging researchers to test new ideas.

<sup>&</sup>lt;sup>19</sup>The VA/DOD Evidence-Based Practice Work Group issues joint VA/DOD clinical practice guidelines—tools that provide guidance and evidence-based recommendations to clinicians regarding the most effective interventions and services for a variety of health care topics. To develop or update a clinical practice guideline, there is a standardized process to ensure that systematic reviews of relevant research outcomes are conducted in order to formulate evidence-based recommendations for prevention, assessment, and treatment services. As of November 2019, there are 21 current clinical practice guidelines.

#### VA's ORD Sets National Research Priorities Based on External and Internal Input

At the national level, ORD leadership sets VA's overall research priorities based on input from internal and external stakeholders and other factors. ORD sets these priorities annually, and its priority-setting process involves discussions with stakeholders and reviews of relevant VA data, according to ORD officials. For example, ORD sets priorities using the following methods:

- Input from internal VA stakeholders. The directors of ORD's research services provide input to the Chief Research and Development Officer on issues they see as priorities. Officials outside of ORD, such as the leadership of VA's new Office of Discovery, Education, and Affiliated Networks, of which ORD is a part, and other VA leaders also provide input, according to ORD officials.
- Input from external stakeholders. ORD officials said they also consider input from the National Research Advisory Council, a 12-member federal advisory committee that provides advice to VA on its research and development efforts, such as recommending which topics to include among the agency's research priorities.<sup>20</sup> According to ORD officials, the office also obtains input on research priorities by meeting with veterans service organizations and by hearing from veterans through veterans' engagement opportunities. In addition, Congress provides direction and input on topics that VA should study, such as through legislation or committee reports.
- **Other factors.** ORD officials said, for example, they set research priorities using VHA data on the prevalence of health conditions among veterans and Veterans Benefits Administration data on military deployment-related conditions.

<sup>&</sup>lt;sup>20</sup>The National Research Advisory Council meets about four times per year, and issues reports to VA on its research program. The Council consists of members of the public, appointed by the Secretary, with demonstrated civic or professional achievement and experience with the provision of veterans' benefits and services. Membership is to include individuals from a variety of geographic areas and ethnic backgrounds, from veterans service organizations, with combat experience, and women. VA has stated that it seeks VA- and non-VA experts with qualifications to deal effectively with research and development issues. According to VA, the types of expertise that may be represented on the Council include biomedical, rehabilitation, health services, and clinical research; geriatric and primary care; special veterans' population health; mental health; occupational health; and surgery, among others. Solicitation of Nomination for Appointment to the National Research Advisory Council, 84 Fed. Reg. 37,394 (July 31, 2019). Under the Federal Advisory Committee Act, the term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group that is established by statute or by the President in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government. See 5 U.S.C. App. (Federal Advisory Committee Act).

Based on stakeholder input and other factors, ORD established three types of national research priorities: strategic, cross-cutting clinical, and other priorities. (Figure 1 shows these research priorities for fiscal years 2019 and 2020.) As of October 2019, ORD officials told us they were determining what these priorities will be for fiscal year 2021.

#### Figure 1: Department of Veterans Affairs' (VA) National Research Priorities, Fiscal Years (FY) 2019 and 2020

To set national research priorities, VA considers input from internal stakeholders (e.g. agency leaders), external stakeholders (e.g. National Research Advisory Council<sup>a</sup>), and other factors (e.g. data on veterans' health conditions).



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| Strategic priorities<br>(FY19-20)  | Cross-cutting clinical priorities<br>(FY19-20)  | Other priorities<br>(FY20)   |
| <ul> <li>Increase the substantial real-world impact of VA research</li> <li>Increase veterans' access to high-quality clinical trials</li> <li>Put VA data to work for veterans<sup>b</sup></li> </ul> | <ul> <li>Gulf War illness</li> <li>Opioids</li> <li>Post-traumatic stress disorder</li> <li>Suicide prevention</li> <li>Traumatic brain injury (TBI)</li> </ul> | <ul> <li>Address the prosthetic<br/>needs of women veterans</li> <li>Contribute to the understanding<br/>of cancer in veterans</li> <li>Address the effects of<br/>service-related exposures</li> <li>Explore the use of exoskeletons<br/>in the context of stroke and TBI°</li> <li>Increase public access to<br/>scientific publications and digital<br/>data from VA-funded research</li> <li>Reduce, replace, and refine the<br/>use of canines in research<sup>d</sup></li> </ul> |

Source: GAO summary of VA information. | GAO-20-211

<sup>a</sup>The National Research Advisory Council is a 12-member federal advisory committee that provides advice to VA on its research and development efforts, such as recommending which topics to include among the agency's research priorities.

<sup>b</sup>In fiscal year 2019, this priority was originally called "Transform VA data into a national resource." VA officials said they renamed it to better communicate their goal of leveraging VA data to improve care for veterans.

<sup>c</sup>VA has been studying the use of exoskeletons—motorized prostheses that are worn outside a person's clothes and provide powered hip and knee motion—to help veterans with spinal cord injury stand and walk. According to VA, exoskeletons may also benefit veterans with other disabling conditions.

<sup>d</sup>Canines can serve as animal models for research. VA is seeking to reduce the use of canines in research while not compromising the ability to conduct cutting-edge research that benefits veterans.

- Strategic priorities are broad long-term priorities that focus on VA's research capability, resources, and operations, rather than on specific clinical conditions, according to ORD officials. For example, one of VA's strategic priorities is to "put VA data to work for veterans." As part of this priority, VA aims to improve its ability to leverage the agency's medical data to improve veterans' care. ORD officials said they plan to revisit these priorities about every 5 years, though the specific initiatives that fall within each priority can change annually. As an example of how the initiatives within the strategic priorities can change, ORD officials said that given VA's plans to implement a new electronic health records system, the National Research Advisory Council advised ORD in 2019 to focus on mitigating any unintended consequences of this transition on research, as part of the strategic priority on data.<sup>21</sup> ORD officials said that as a result of this input, they are increasing the intensity and scope of their efforts pertaining to this transition.
- Cross-cutting clinical priorities, in contrast, focus on predominant clinical conditions seen in veterans and can change yearly, according to ORD officials. For example, one current cross-cutting clinical priority is PTSD. As part of this priority, VA supports research to better understand the underlying biology of PTSD, refine approaches for diagnosing this condition, and develop and test new treatments. ORD officials said they plan to add precision oncology as a new crosscutting clinical research priority for fiscal year 2021, based on input

<sup>&</sup>lt;sup>21</sup>VA has used the same health information system— VistA—for over 30 years. VA has pursued multiple efforts to modernize this system, and those efforts have not been completed. In June 2017, VA announced it would redirect efforts to replace the VistA electronic health record. VA plans to adopt the same commercial system that DOD is currently acquiring—Cerner Millennium—and to continue using VistA during the decade-long transition to the Cerner system. See. GAO, *Electronic Health Records: VA Needs to Identify and Report System Costs*, GAO-19-125 (Washington, D.C.: July 25, 2019).

from VA leadership.<sup>22</sup> ORD officials also said they plan to broaden the Gulf War illness cross-cutting clinical priority to include the effects of military service-related toxic exposures, more generally. This planned change is based in part on veterans service organization and Gulf War veteran input.

• Other priorities are those that VA will focus on in the near term, based primarily on input from Congress, veterans service organizations, and other non-ORD stakeholders, according to ORD officials. For example, several of these priorities for fiscal year 2020—such as addressing the prosthetic needs of women veterans and exploring ways to use an "exoskeleton" for veterans who have experienced strokes or traumatic brain injury (TBI)—were identified by Congress as research needs.<sup>23</sup>

ORD's Four Research Services Set Their Own Priorities Based on National Priorities and Veterans' Specific Needs and Conditions In addition to national priorities for research funding, ORD permits its four research services to set their own service-level research priorities, which are based in part on the national priorities. According to ORD officials, the directors of the four ORD research services—the biomedical laboratory, clinical science, health services, and rehabilitation research and development services—have latitude to set their own priorities, given their expertise in, and the particular focus of, their respective research areas.<sup>24</sup> These directors told us they may consider a range of internal and external factors when setting priorities, including:

<sup>22</sup>Precision oncology involves molecular profiling of cancer tumors to identify specific ways to target them.

<sup>23</sup>In the committee report accompanying the bill H.R. 5786, Making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending 2019, and other purposes, the House Committee on Appropriations stated that there is an acute need for research specializing in female prosthetics, as most prostheses are designed to fit male veterans. The Committee stated that a proportionate amount of prosthetics research should be focused on prosthetics meant for female veterans. See H.R. Rep. No. 115-673 at 51 (2018). VA also has been studying the use of exoskeletons—motorized prostheses that are worn outside a person's clothes and provide powered hip and knee motion—to help veterans with spinal cord injury stand and walk. According to VA, exoskeletons may also benefit veterans with other disabling conditions.

<sup>24</sup>For this discussion, we are referring to the directors of four ORD services: the Biomedical Laboratory Research and Development Service, Clinical Science Research and Development Service, Health Services Research and Development Service, and Rehabilitation Research and Development Service. The director of a different ORD office that funds research projects—the Cooperative Studies Program—told us that this office follows VA's national research priorities and does not set specific cross-cutting clinical priorities due to the nature of the program, which supports large-scale clinical trials and receives fewer research study proposals than other ORD services.

Internal factors. The four research service directors told us they take • into account VA's national research priorities when determining their priorities. For example, the director of the biomedical laboratory service identified VA's five cross-cutting clinical research priorities as priorities for this research service. Also helping shape research priorities are VA stakeholders, such as the Secretary of VA and scientific program managers-the ORD staff who are responsible for specific topic areas within their services. In addition, service directors told us they use VA data on veterans' health conditions when setting research priorities. The leadership of ORD's rehabilitation research service, for example, told us they review VA data on the top serviceconnected conditions for which veterans are receiving disability benefits, and take that factor into consideration, along with less prevalent conditions such as spinal cord injuries, that also have a significant impact on veterans' function and independence when setting priorities.<sup>25</sup> (See text box for examples of research projects on spinal cord injury, which is one of the rehabilitation research service's priorities.)

<sup>&</sup>lt;sup>25</sup>Rehabilitation research service officials said they refer to the Veterans Benefits Administration's (VBA) Annual Benefits Reports, which describe VBA benefit programs and the population of veterans and dependents that receive VBA benefits. As of October 2019, the most recent such report was the VBA Annual Benefits Report FY2018 (https://www.benefits.va.gov/REPORTS/abr/, accessed Oct. 16, 2019).

#### Exoskeleton-assisted walking

Exoskeletons are motorized prostheses that are worn outside a person's clothes and provide powered hip and knee motion, to help veterans with spinal cord injuries stand and walk. In this photograph, a research participant with a spinal cord injury uses an exoskeleton at the Bronx VA medical center.



Source: VA (information and photo). | GAO-20-211

#### Department of Veterans Affairs (VA) Research on Spinal Cord Injuries

VA provides care for about 27,000 veterans with spinal cord injuries. Veterans with spinal cord injuries may have secondary bone loss, muscle atrophy, and other conditions. They also have an increased prevalence of diabetes, heart disease, stroke, bowel and bladder incontinence, chronic pain, and reduced quality of life, according to VA.

VA's National Center for the Medical Consequences of Spinal Cord Injury, located at the Bronx VA medical center, is one of the VA's rehabilitation research service's research centers. The Center's mission is to improve quality of life and increase longevity in individuals with spinal cord injuries by identifying and intervening to reduce and prevent the secondary consequences of spinal cord injuries. Examples of the Center's VA-funded research include:

- Studying the safety and efficacy of exoskeleton-assisted walking in rehabilitation settings and in home and community environments,
- Developing and testing innovative approaches to improve bowel function,
- Studying the impact of low blood pressure and developing approaches to help individuals maintain normal blood pressure,
- Studying individuals' difficulties regulating their body temperature, and developing interventions to address this problem, and
- Using magnetic and electrical stimulation to enhance arm and leg function.

Source: GAO summary of VA information. | GAO-20-211

• External factors. Congress can play a role in shaping the research services' priorities. For example, the health services research service has identified research on policies and programs included in recently enacted legislation, including the VA MISSION Act of 2018 and the Comprehensive Addiction and Recovery Act of 2016, as a priority.<sup>26</sup> Input from other federal partners, such as the National Institutes of Health (NIH) or the Department of Defense (DOD), also can influence the priorities of ORD's research services. Officials with the rehabilitation research service, for example, said they meet with DOD officials about research efforts and that input from DOD on the health issues seen among active-duty service members can help them

<sup>26</sup>The VA MISSION Act of 2018, enacted in June 2018, required, among other things, VA to establish a permanent community care program in which eligible veterans can obtain health care services from providers in the community. Pub. L. No. 115-182, 132 Stat. 1393 (2018). The health services research service expressed an interest in research on key provisions of the Act, such as implementation of the community care program, coordination of VA and non-VA care, and virtual care (e.g., telemedicine). The Comprehensive Addiction and Recovery Act of 2016 requires VA to implement a number of efforts aimed at improving opioid safety for veterans. Pub. L. No. 114-198, 130 Stat. 695 (2016). Related areas of interest to the health services research service included, for example, studies on treatment of long-term opioid users, and safety and efficacy related to long-term opioid therapy among aging veterans and veterans with mental health conditions.

anticipate what health issues those service members might face when they transition to veteran status. They can then use that information when deciding which clinical areas to prioritize. In addition, one director said that input from veterans service organizations can shape research priorities, while another director obtains input from veterans through a VA veteran engagement group that provides information on the needs of veterans.

ORD's service-level research priorities cover a wide range of areas, such as service-connected conditions and conditions that veterans may experience as they age. As of October 2019, the services had each identified between 10 and 20 research priorities.<sup>27</sup> (See the box below for examples.)

| Examples of Office of Research and Development's Service-Level Research Priorities, as of October 2019 |
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- **Traumatic brain injury (TBI)** is a research priority for all the services. For example, the effect of prolonged opioid use on TBI outcomes is a priority for the rehabilitation research service.
- **Post-traumatic stress disorder (PTSD)** is a research priority for several services. For example, PTSD and the conditions that commonly co-occur with this condition is a priority for the clinical science research service.
- Spinal cord injuries are a research priority for some services.
   For example, disability—including spinal cord injury and TBI is a priority for the health services research service.
- Suicide prevention is a research priority for multiple services. The biomedical laboratory service, for example, has an emphasis on biological markers of suicide.
- Aging-related issues are a research priority for several services. For example, "long-term care, aging, and caregiver support" is a priority for the health services research service.

 Pain is a research priority for all the services. For example, pain mechanisms and treatments, including alternatives to opioids, is a priority for the clinical science research service.

Source: GAO summary of VA information | GAO-20-211

ORD Uses a Range of Approaches to Incorporate Priorities When Funding VA Research Once priorities are set, ORD officials told us they use a range of approaches to incorporate those priorities when funding research projects, such as: encouraging researchers to study priority topics, considering priorities when deciding which projects to fund, and funding collaborative research efforts that are focused on specific priorities. In addition to the research priorities, ORD officials said they also consider other clinical and research needs when funding VA research, such as encouraging researchers to test new ideas in clinical areas that are not identified as priorities but are still important to veterans' health.

<sup>&</sup>lt;sup>27</sup>The services' priorities included clinical topics ranging from individual conditions such as PTSD to broader types of conditions or topics, such as deployment health, women's health, and virtual care (e.g. telehealth). The health services research service also identified priorities pertaining to VA-related legislation and to research methods such as measurement science.

ORD officials' approaches to incorporating priorities when funding research included the following examples:

Encouraging researchers to study priority topics. ORD's research services highlight their research priorities in their requests for research proposals. In some cases, they use targeted requests for research proposals solely on priority topics. In fiscal year 2019, ORD issued targeted requests for proposals linked to priorities such as suicide prevention, TBI, and the VA MISSION Act. In other cases, the research services highlight their research priorities in general requests for applications, which permit VA researchers to submit proposals on both priority and non-priority topics. For example, in 2019, the rehabilitation research service issued a general request for research proposals, stating that four research priorities—the prosthetic needs of women veterans, exoskeleton research related to patients with stroke and TBI, non-pharmacological interventions for chronic pain, and the effects of prolonged opioid use on long-term outcomes from TBI—were of particular interest for that funding cycle. (See text box for examples of VA research projects on priority topics.)

#### Department of Veterans Affairs (VA) Research on Traumatic Brain Injury (TBI) and Stress Disorders

Traumatic brain injury (TBI), a common injury among veterans of conflicts in Iraq and Afghanistan, can lead to a number of physical, cognitive, and emotional problems, such as memory and attention issues. These veterans may also experience post-traumatic stress disorder (PTSD), which can lead to anger, irritability, depression, substance abuse, and other symptoms, according to VA.

VA's Translational Research Center for TBI and Stress Disorders, located at the Jamaica Plain (Boston, Mass.) VA medical center, is one of VA's rehabilitation research service's research centers. The Center seeks to better understand the complex cognitive and emotional problems faced by these returning veterans, with the goal of developing better treatment options. The Center runs a longitudinal cohort study that collects imaging, genetic, and other data on returning veterans. Examples of the Center's VA-funded research projects include:

- A study to assess the efficacy of the STEP-Home program, a 12-week workshop to help veterans who have served in Iraq or Afghanistan. The program aims to strengthen behavioral and emotional skills so that veterans are better equipped to rejoin their families and civilian communities.
- Studies to identify sub-types of PTSD, and to assess the long-term effects of PTSD and mild TBI.
- Research on the use of non-invasive brain stimulation to help patients with PTSD.
- Development of the Boston Assessment of Traumatic Brain Injury- Lifetime tool, a clinical interview to characterize head injuries and diagnose TBI throughout a patient's lifespan.

Source: GAO summary of VA information | GAO-20-211

Considering priorities when deciding which projects to fund.
 Directors from all of ORD's four research services stated that the
 scientific merit of research proposals—based on the proposals'
 significance to veterans' health, feasibility, and other criteria—is a key

factor in funding decisions.<sup>28</sup> Several directors said they may decide to fund a meritorious project that addresses one of their research priorities in lieu of another project that was ranked similarly or higher but does not address a priority. Some of the directors noted that this only applies to a small share of funded projects, but is part of how they align research projects with priorities.

Funding collaborative research efforts. The biomedical laboratory service has funded field-based meetings to plan collaborative multisite research programs to speed the development of treatments for service-related illnesses and injuries. The director of this research service said that in 2019, these research-planning meetings focused on ORD's national research priorities, such as TBI, PTSD, and pain and opioids, among other topics. Also, starting in 2019, the health services research service is providing funding for its research centers to collaborate with other VA researchers on three of its priority areas: suicide prevention, opioid reduction and pain, and access to care. Officials from this research service said they also hold "State of the Art" conferences that can help VA make progress on priority areas. For instance, VA officials held a September 2019 conference on managing pain and addiction, specifically focusing on strategies to improve opioid safety. VA officials said this conference involved a wide range of VA staff and resulted in recommendations about research priorities, including areas where more research is needed.

In addition to the research priorities, ORD officials said they consider other clinical and research needs when determining which health care research efforts to fund. Rehabilitation research service officials specifically noted that if they did not fund research in non-priority clinical areas, it would hinder their goal of encouraging researchers to test new ideas in other areas that are important to veterans' health, which the officials say can lead to discoveries. The importance of innovation was echoed by other ORD officials, as well. Some ORD research service directors said that while new research needs emerge over time—as stakeholders highlight particular clinical needs, or VA leadership

<sup>&</sup>lt;sup>28</sup>For each of ORD's research services, research proposals are evaluated and scored by a panel of reviewers that assesses their scientific merit. To assess scientific merit, reviewers use a range of review criteria, such as the proposals' significance to veterans' health, feasibility, innovation, and the experience of the researchers who would conduct the study. Research proposals are then ranked according to their scores. The directors of the research services decide which proposals to fund. The number and type of proposals funded can depend on a range of factors, such as proposals' rank, the amount of available funding, and research priorities, according to the directors.

changes—it is important for VA research efforts to anticipate veterans' longer-term needs and focus on more enduring issues, too. Officials from one research service said, for example, that they encourage researchers to focus on issues that will still be important in several years, such as women veterans' care, because research can take years to yield results.

In addition, some ORD research service directors said that although service-connected conditions are key parts of their research portfolios, they also work to address other conditions. Clinical science service officials said, for example, that they have a broad charge to support research into any disease or condition that affects veterans' health. One of their priorities is researching diseases with a high health care burden among veterans, which may or may not be related to veterans' military service. Rehabilitation service officials noted that their work focuses on veterans' disabilities and impairments incurred through military service but is not limited to service-connected conditions. The officials said that because VA provides lifetime care to veterans, their research portfolio addresses events that cause impairment and disability throughout a veteran's lifespan, including the aging process. For example, their research portfolio includes research on medical conditions that veterans may experience as they age, such as stroke, and chronic conditions like diabetes and kidney disease.

As part of their efforts to consider multiple clinical and research needs, officials from the health services research service told us they are analyzing their overall research portfolio to determine where more or less research funding may be warranted. The officials explained that as part of their strategic planning efforts, they are identifying any areas they have "under-invested" in, and any areas that have received significant funding in the past but might no longer need that degree of investment. Among other things, they are considering the extent to which research on health conditions is already being done by other research organizations, such as NIH. They noted that while addressing chronic diseases is important to VA and its veteran population, it is possible that research on certain diseases is being covered by other research partners. In contrast, they said, there are areas where VA may have a unique ability to contribute to research because of its nationwide health care system or because it is ahead of the curve in health care trends, such as in telehealth and in integrating mental health care into primary care settings. Officials said their portfolio analysis could result in some "resetting" of research priorities and funding after the analysis is completed in 2020.

Looking forward, ORD officials shared examples of approaches they are taking to boost the agency's ability to address its research priorities. For example, ORD officials said there are a limited number of VA researchers working in certain priority areas, such as suicide prevention, which the officials said can hinder their efforts to fund new research projects. Among the efforts to boost the number of researchers working on priority areas, officials from one research service said they recently began incorporating their research priorities into the service's Career Development Program funding awards. In addition, in 2019, ORD implemented a new method to spur and track ORD progress in addressing priorities. According to ORD leadership, as part of this method, ORD staff will identify the actions and resources needed to address specific priorities, and meet quarterly with the Chief Research and Development Officer to review their progress and identify next steps.

ORD's QUERI Program and Other VA Entities Facilitate Translating Research into Clinical Practice VA has a variety of efforts to facilitate translating research findings into clinical practice to improve the care veterans receive. These efforts include those undertaken by ORD's QUERI program, its health services research service, and VA's Diffusion of Excellence Initiative, as discussed below.

**ORD's QUERI provides a link between the research program, VA program offices, and VA providers.** According to the QUERI director, QUERI serves as the center of VA's efforts to translate research into clinical practice. QUERI's overall mission is to improve veteran health by rapidly implementing research findings and interventions into clinical practice. QUERI is housed within ORD, but funded separately by non-research dollars.<sup>29</sup>

QUERI facilitates research implementation through activities such as the National Network of QUERI programs. According to the director of QUERI, these programs are partnered with VA national program offices, and they take various practices—often identified or developed through VA studies—and implement them at the regional or national level. For example, through its "Bridging the Care Continuum" QUERI investigators focus on improving the health of vulnerable veteran populations, such as

<sup>&</sup>lt;sup>29</sup>According to the FY16-20 QUERI Strategic Plan, QUERI is supported through specific purpose funds (i.e., VA medical services/administration funds). The QUERI specific purpose funding is currently reviewed and approved annually by the VHA National Leadership Board and managed by the Office of Research and Development.

homeless veterans, by implementing a co-occurring mental health and substance use treatment within multiple VA medical centers. (See text box for an example of implementation through a QUERI National Program.) In addition, QUERI funds resource centers with technical experts who can help promote and review best practices for implementation. Specifically, one resource center—the Center for Evaluation and Implementation Resources in Ann Arbor, Mich.—is available to VA researchers for consulting on strategies to translate research.

### Example of Quality Enhancement Research Initiative (QUERI) Research Translated into Clinical Practice: Telemedicine Outreach for Post-Traumatic Stress Disorder (PTSD) in Small Rural Community-Based Outpatient Clinics

The goal of the Virtual Specialty Care QUERI National Program is to implement and evaluate promising clinical practices that incorporate technologies to improve access to specialty care for veterans in rural settings. One example of its efforts is the telemedicine program, based on VA-funded research demonstrating the effectiveness of using telemedicine outreach for veterans with PTSD. The Office of Rural Health and the Virtual Specialty Care QUERI partnered to implement this telemedicine program which provides evidence-based psychotherapy for veterans with PTSD via interactive video either from their homes or at community-based outpatient clinics, and connects veterans with care managers to coordinate their treatment. According to VA, as of June 2019 the telemedicine program is being implemented in six states and 1,073 "hard to reach" veterans have been engaged via the program.

Source: GAO summary of information from Department of Veterans Affairs (VA) | GAO-20-211

In 2019, QUERI published the "Implementation Roadmap," a new resource—intended for a variety of users, including researchers, clinicians, and leadership—to advance research translation at VA and provide information on how to identify, implement, and sustain evidence-based practices to improve the quality of care for veterans. The Roadmap outlines the different stages of research implementation, specifically delineating when research is ready to be implemented into clinical practice.<sup>30</sup> The QUERI director told us staff created the Roadmap as a teaching tool to provide guidance on how to implement research at VA and when to collaborate with QUERI. In addition, the director of QUERI told us the Roadmap demonstrates the cyclical nature of research and how implementation is part of a continuous scientific process, not an "end game." QUERI officials said that throughout the process of

<sup>&</sup>lt;sup>30</sup>The Implementation Roadmap has three stages for implementing an evidence-based practice: 1) pre-implementation focuses on converting data to knowledge by identifying a problem and applicable evidence-based practices, 2) implementation focuses on finding implementation strategies and benchmarks to measure successful implementation, and 3) sustainment includes evaluating the practice and creating a plan of how it will be sustained over time. See A. M. Kilbourne et al., "Quality Enhancement Research Initiative Implementation Roadmap: Toward Sustainability of Evidence-based Practices in a Learning Health System," *Medical Care*, vol. 57, no. 10 Suppl 3, (2019).

implementation, new research questions might be generated, which QUERI can use to inform further investigation or follow up studies.

**ORD's health services research service funds studies that focus on direct application of research in clinical practice.** ORD's health services research service supports research translation by funding studies focused on how interventions work in "real world" settings and on implementing VA research findings into clinical practice. For example, little is known about the quality of non-VA care for sex-specific services such as mammography, according to VA, despite increasing numbers of women veterans relying on such care due to limited availability within VA. One study funded by this research service looked at strategies for provision, coordination, and quality of oversight of non-VA care for women, and assessed perceptions and experiences with non-VA care among women veterans.<sup>31</sup> Among other things, the study found VA sites providing mammography were more likely to notify women more quickly of abnormal results than non-VA sites, but non-VA sites were more likely to meet guidelines for timely follow-up.

In addition to funding individual research studies through merit review, the health services research service funds 18 Centers of Innovation (COIN), each of which focus on one or more areas of research that address questions significant to clinical and operational partners. For example, officials from the dual-site COIN in Seattle and Denver, which focuses on veteran-centered and value-driven care, told us they are participating in a study co-funded by VA, NIH, and DOD evaluating non-pharmacological options to treat pain and co-occurring mental health conditions in veterans with chronic pain; the study will be overseen by VA's Office of Patient-Centered Care and Cultural Transformation. According to the research service officials, the COINs are designed to bring researchers from multi-disciplinary research teams together to engage in research and establish partnerships that can affect VA policies, practices, and health care outcomes. (See text box for an example of research funded by the health services research service that has been translated into clinical practice.)

<sup>&</sup>lt;sup>31</sup>In instances where specialized, gender-specific services (e.g. mammography and prenatal care) are not available within VA, federal law enables VA to pay for veterans' care at outside facilities. 38 U.S.C. § 1703.

#### Example of Research Translated into Clinical Practice across VA: Reducing Catheter-Associated Urinary Tract Infections

The Center for Innovation (COIN) in Ann Arbor, Mich., partners with VA clinical, policy, and operations leaders to implement and evaluate ways to make health care safer, more effective, and affordable for veterans. For example, an investigator from this COIN, funded in part through a Career Development Award, conducted research on enhancing patient safety by reducing catheter-related infections. Then, in partnership with another VA researcher, this investigator conducted a study funded by the health services research service and created a "bundle" of activities to implement in VA hospitals throughout Michigan. This included removing catheters as soon as possible and increasing the use of recommended infection control practices. VA researchers assisted the National Center for Patient Safety in implementing the practices, and the success of the "bundle" resulted in its national implementation in more than 1,000 hospitals. VA reported that catheter-associated urinary tract infection rates decreased by 32 percent in participating general medical and surgical units.

Source: GAO summary of information from Department of Veterans Affairs (VA) | GAO-20-211

According to officials from the health services research service, in addition to funding studies and COINs, the service maintains four resource centers, which provide support to VA researchers in several areas, including data, health economics, and dissemination.<sup>32</sup> For example, the Center for Information Dissemination and Education Resources circulates research findings through VA newsletters, cyberseminars, and publications and educates clinicians and researchers on sharing findings. In addition, the center coordinates meetings and conferences—such as the service's joint national conference with QUERI—which provides an opportunity for VA researchers to present scientific findings and discuss the implementation of findings into practice. In 2017, the conference focused on accelerating the adoption and spread of practices and improving VA's ability to utilize healthcare data to enhance care for veterans.

Officials from the health services research service told us that, starting in 2019, they began implementing two new strategies to increase the impact of VA research on veterans' health care. First, the service began a new effort to bring together and fund consortiums of researchers from multiple COINs each with a particular focus on implementing evidence-based practices in a given priority area. VA officials told us that as of October 2019, the health services research service established two consortiums of researchers to focus on suicide prevention and opioids and pain management. The service is planning to add two additional consortiums in 2020 to focus on access to care and telehealth and connected care.

<sup>&</sup>lt;sup>32</sup>The VA Informatics and Computing Infrastructure (VINCI) provides access to VA's national data warehouse; the VA Information Resource Center (VIReC) educates researchers on how to best use VA data; and the Health Economics Resource Center (HERC) works on economic issues, including developing cost tools for studies on cost effectiveness and budgetary impacts.

Second, in 2019 the research service provided additional funding opportunities for COINs to submit research proposals that include fiveyear goals for the impact of their research, such as VA policy changes or spreading the research to additional sites, and yearly milestones for achieving those goals. Per the request for applications, applicants' proposals must provide information on how the COINs plan to apply health services research methods, including implementation research. According to VA, as of October 2019, 20 proposals had been selected to receive funding through this new strategy.

Diffusion of Excellence Initiative aims to encourage practitioner implementation of research-based practices outside of ORD. VA's Diffusion of Excellence Initiative, created in 2015, established an annual competition-known as VA's "Shark Tank"-to engage employees in implementing innovative practices that will positively impact veterans. According to officials from the Diffusion of Excellence Initiative, many of these practices are based on evidence-based research. Under the competition, "investors" (directors from VA medical centers and VISNs) make offers on practices that have been successfully implemented in at least one VA medical center, and the winning investor receives facilitated implementation support so that the practice can be implemented at the investor's medical center.<sup>33</sup> The officials told us that several of these practices have been identified as exemplary practices and are now being used nationally across multiple VA health care settings. For example, they described one such practice, a tooth-brushing routine implemented for hospitalized veterans to decrease the risk of oral bacteria getting into the veterans' lungs, which research had shown could increase their risk of pneumonia. According to officials from the Diffusion of Excellence Initiative, the practice decreased hospital-acquired pneumonia by 90 percent at the pilot site, and is being implemented in other VA health care settings.

Other VA efforts to facilitate research translation into clinical practice. In addition to the changes to the existing efforts for facilitating research translation, VA has recently taken other actions to help ensure

<sup>&</sup>lt;sup>33</sup>VA officials told us that the Diffusion of Excellence Initiative solicits submissions of promising evidence-based practices from VA staff. The submitted practices are reviewed by evaluators over two rounds, and the finalists selected for the final round present their practices in front of the investors. Investors from VA medical centers make offers for the opportunity to implement the practice. Offers are often multi-faceted and have included a wide range of support from dedicated personnel time to travel support.

|  | findings from VA research are integrated into practice. In response to ORD's current strategic priority to "increase the substantial real-world impact of VA research," the director of ORD established a workgroup to create "The Research Lifecycle," which was published in October 2019. <sup>34</sup> The lifecycle is a resource that specifies processes to help move research to direct application in routine clinical care. It describes the research and implementation process from identifying innovations that align with clinical priorities to ensuring practices are sustained in clinical care, beyond research and implementation. For example, one phase of the process involves evaluating interventions to determine if they are ready to be implemented into clinical practice. The director of QUERI told us that the information in the publication is broadly applicable across all ORD research and that like the QUERI Implementation Roadmap, the publication reiterates that research is a continuous process rather than a straight line with an endpoint. In addition to the research lifecycle, an official from the agency's Cooperative Studies Program—which funds large, multi-center clinical trials—told us the program established a new requirement in 2019 that research proposals include an implementation plan. The goal of this change is to encourage researchers to think about research translation from the beginning—and how their work might be translated into clinical practice, according to the program official. Researchers planning to conduct these types of clinical trials will have the opportunity to consult with internal implementation experts to develop plans to translate the research into clinical practice, according to ORD officials. |
|--|---|
| VA Officials Described<br>Efforts to Coordinate<br>on VA Research<br>Priority Setting and<br>Translation | VA officials from both ORD and the national program offices we spoke<br>with described their experiences coordinating on research. Coordination<br>can help both to inform research priorities to make them most useful and<br>applicable, and to encourage the translation of research into clinical<br>practice, which can help VA meet its broader goal of ensuring its research<br>is benefiting veterans' health.  |
|  | <sup>34</sup> The lifecycle was created by the Research to Real-World workgroup, which was commissioned by ORD leadership to develop recommendations that lead to substantial real-world impacts of research to ensure that veterans benefit from research at VA. The workgroup includes representatives from multiple VA program offices, as well as ORD. See A.M. Kilbourne et al., "Research Lifecycle to Increase the Substantial Real-world Impact of Research Acedersting Impacts of Acedersting to Application." <i>Medical Care</i> and <i>See</i> 10.  |

Impact of Research: Accelerating Innovations to Application," *Medical Care*, vol. 57, no.

10 Suppl 3, (2019).

National program offices—such as those for clinical specialties including mental health or spinal cord injury care-provide input to ORD both on research priorities and on efforts to translate research findings into clinical practice within their respective issue areas. For example, officials from the Office of Mental Health and Suicide Prevention told us that their lead staff for suicide prevention participated in strategic planning efforts with ORD to determine a "road map" for current and future research in this area.<sup>35</sup> This VA program office official described working with ORD to provide clinical perspective on gaps in research and clinical care related to suicide prevention, among other things. Given the disproportionately higher rate of suicide among veterans compared with the civilian population, such coordination can help maximize VA's efforts both in research and in clinical care. Among other things, the road map identifies remaining questions related to suicide prevention to be addressed by VA and other researchers, categorized by type of research (e.g., epidemiological or intervention).

Coordination between the research program and national program offices also can facilitate the conduct of the research itself, encouraging research that is viable and relevant to be conducted and translated into practice. For example, ORD leadership told us that program office buy-in on VA research priorities and efforts can lead to VA clinicians being more willing and able to participate in VA research. ORD leadership also told us that ORD has recently begun requesting that researchers engage and collaborate with relevant program offices during the planning process for large multi-site clinical trials, including seeking input from program offices on research proposals. Potential questions for researchers to ask include: does the relevant program office think the proposal's topic is clinically important; is the research proposal feasible; and will it answer a question that is important from a clinical perspective? According to ORD officials, because VA funds a small number of these types of trials—which are intended to provide a definitive answer to a clinical question—researchers

<sup>&</sup>lt;sup>35</sup>VA developed the *Suicide Prevention Research Roadmap: Transition to Veteran Status* to align with the *Joint Action Plan for Supporting Veterans during their Transition from Uniformed Service to Civilian Life*. Executive Order 13822 required VA, the Department of Defense, and the Department of Homeland Security to submit to the President such a Joint Action Plan, which describes actions to provide seamless access to mental health care and suicide prevention resources for transitioning uniformed service members, specifically emphasizing access to services during the first year period following discharge, separation, or retirement from military service. Exec. Order No. 13822, 83 Fed. Reg. 1513 (Jan.9, 2018).

want to be sure the studies are relevant to the needs of the program offices.

One specific example both ORD and program office officials provided was related to their coordination on research on osseointegration—a medical procedure through which a metal rod is inserted into the bone at the site of an amputation, allowing a prosthetic limb to be attached through the skin directly to the remaining bone of the amputated limb. Officials from the rehabilitation research service told us that they have been working with program office officials to consider aspects of implementation prior to beginning a clinical trial, including the availability of the surgical procedure throughout VA and the types of post-operative care patients would need. These officials told us that their goal is to ensure the clinical trial is designed for translation.

In addition, because national program offices establish policies that affect the provision of care across VA, program office officials told us that collaboration with ORD can help them to incorporate evidence-based practices in developing and rolling out these policies. For example, an official from the Spinal Cord Injury and Disorders System of Care program office told us that it incorporated research findings when it revised its national policy—including a new requirement for all spinal cord injury centers to have vocational rehabilitation counselors on staff. A program office official told us that the addition of this requirement resulted from VA research—led by a researcher clinician—that found that veterans with spinal cord injuries who received specialized vocational support services had the best chance of success for job placement and continued employment.<sup>36</sup> In another example, ORD officials told us that VA researchers were serving as subject matter experts to the national program office developing the protocol and clinical guidelines for

<sup>&</sup>lt;sup>36</sup>Because spinal cord injuries can affect many different areas of daily living, a large number of veterans with these types of injuries have difficulty finding work and staying employed. Specifically, VA researchers found in one study that veterans with spinal cord injuries who received specialized vocational support were more than twice as likely to become employed compared with those who did not. See, L. Ottamanelli et al., "Effectiveness of Supported Employment for Veterans with Spinal Cord Injuries: Results from a Randomized Multisite Study," *Archives of Physical Medicine and Rehabilitation*, vol. 93, no. 5 (2012): p. 740-7.

implementing intranasal ketamine as a new treatment for certain veterans with treatment-resistant depression.<sup>37</sup>

ORD and program office officials described using both informal and formal approaches to coordinate on research priorities and translation. For example, program office officials told us about occasional participation of ORD staff in their regular meetings and calls, as well as relationships between program office staff and individual researchers. ORD officials from one service told us that their scientific portfolio managers serve as a sort of liaison between researchers and clinical program office partners. These officials told us that because VA's research program is intramural, there is an ongoing discussion with researchers and others within VA in setting research priorities.

Although VA officials were mostly positive in describing coordination between the research program and program offices, some officials noted opportunities for improvement, as well. Specifically, officials from the three national program offices we spoke with said it would be beneficial to have a more formal or systematic approach for coordination with ORD. An official from one national program office said a more systematic process would be helpful, so that collaboration is not so dependent on individual relationships or personalities. Officials from another national program office noted that they considered having one staff person as a dedicated resource to liaise with ORD, but lacked resources to do so.

Given limited time and competing priorities for researchers and program office officials, ORD officials told us that it would be best to focus on strategic coordination, and noted that some such efforts are underway. Specifically, ORD leadership acknowledged that it would be helpful for ORD and program offices to engage more in general—particularly related to ORD's research priorities. However, because ORD leadership said it would not be efficient to have to go "door to door" to each individual program office or VISN to have those discussions, it would be more helpful to find more strategic ways to engage. For example, ORD leadership said that ORD's inclusion in larger annual VHA strategic

<sup>&</sup>lt;sup>37</sup>Intranasal ketamine is an anesthetic that is administered in the form of a nasal spray under supervision of a health care professional, due to potential side effects of sedation and dissociation. According to ORD officials, the program office is seeking VA research assistance in developing clinical guidelines for this form of ketamine, given its recent approval by the Food and Drug Administration, because ORD and some of its researchers have particular expertise on ketamine, due to clinical trials on other forms of the drug, as well as experience in convening expert panels on the topic.

planning sessions could be a way to facilitate strategic coordination. Similarly, health services research service officials told us that service's new effort to build consortiums of researchers focused together on a particular priority area may also facilitate coordination between researchers and clinical program offices, particularly on key topics for VA, such as suicide prevention and opioids. In addition, ORD leadership told us that ORD is focusing its efforts on "big ticket items"—such as larger studies or clinical trials through the Cooperative Studies Program—where there can be a big impact through collaboration with program offices, because a single study generally does not lead to changes in clinical practice.

Another mechanism available to facilitate strategic coordination between the research program and national program offices is ORD's QUERIparticularly its Partnered Evaluation Initiatives-through which researchers partner with national program offices to evaluate specific initiatives with potentially high impact on VA national policy.<sup>38</sup> For example. QUERI investigators have partnered with the Office of Mental Health and Suicide Prevention to evaluate an upcoming initiative to send "caring letters" to veterans who have called the Veterans' Crisis Line and have been engaged in VA care recently. Caring letters, letters noting that the veteran is cared about and matters, are an intervention shown to be effective in reducing suicides in various at-risk populations.<sup>39</sup> In addition, VA program office officials told us that while most VA program offices have their own internal program evaluation services, they do not have sufficient resources to evaluate the effectiveness of all of their programs and policies, motivating them instead to work with QUERI and ORD. For example, the Office of Mental Health and Suicide Prevention has also partnered with QUERI on the STAR VA program, to examine non-

<sup>&</sup>lt;sup>38</sup>Through QUERI's Partnered Evaluation Initiatives, national program offices or other VA entities partner with QUERI and co-fund evaluations of the implementation of practices of interest, including an assessment of the status of implementation, factors or conditions that affect implementation, and the impact of the initiative on patient experience, quality of care, etc.

<sup>&</sup>lt;sup>39</sup>VA's "caring letters" include information about available resources. According to VA, the "caring letters" intervention for suicide prevention is an evidence-based intervention that is currently one of only two suicide prevention strategies that have reduced suicide rates in a randomized controlled trial. The results of a recent VA study suggest that most high-risk veterans would perceive the intervention as helpful and caring, and provided information on how to successfully implement the intervention for a veteran population. See M.A. Reger et al., "Veteran Preferences for the Caring Contacts Suicide Prevention Intervention," *Suicide and Life Threatening Behavior*, (2018).

|                 | pharmacological approaches to treating agitation and other issues in veterans with dementia. Program office officials told us that they can the results of these evaluations to influence policy, standard operatin procedures, and treatment in the field.  |  |
|-----------------|--|--|
|                 | In summary, VA is uniquely positioned to implement research into clinical practice because of the research program's adjacency to such a large, integrated health care system. As we have noted, coordination between the research program and partner entities could help ensure VA-funded research results in the spread and adoption of evidence-based practices. VA recognizes the importance of this coordination and continues to actively pursue effective coordination strategies. |  |
| Agency Comments | We provided a draft of this report to VA for review and comment. VA provided technical comments, which we incorporated as appropriate.   |  |
|                 | We are sending copies of this report to the Secretary of the Department<br>of Veterans Affairs and other interested parties. In addition, the report is<br>available at no charge on the GAO website at http://www.gao.gov.  |  |
|                 | If you or your staff have any questions about this report, please contact<br>me at (202) 512-7114 or farbj@gao.gov. Contact points for our Offices of<br>Congressional Relations and Public Affairs may be found on the last page<br>of this report. GAO staff who made key contributions to this report are<br>listed in appendix III.  |  |
|                 | Sincerely yours,   |  |
|                 | Jessica Faits  |  |
|                 | Jessica Farb   |  |
|                 | Director, Health Care  |  |

## Appendix I: Department of Veterans Affairs (VA) Locations Selected for Site Visits

#### Table 2: Department of Veterans Affairs (VA) Locations Selected for Site Visits

| Location VA medical center |                                   | VA centers and programs   |  |  |  |
|----------------------------|-----------------------------------|---|--|--|--|
| Ann Arbor,                 | Ann Arbor VA medical center       | Center for Evaluation and Implementation Research                                   |  |  |  |
| Mich.                      |                                   | Center for Clinical Management Research   |  |  |  |
|                            |                                   | <ul> <li>PeRsonalizing Options through Veteran Engagement</li> </ul>                |  |  |  |
| Boston, Mass.              | Jamaica Plain VA medical center   | Center for Information Dissemination and Education Resources                        |  |  |  |
|                            |                                   | Center for Healthcare Organization and Implementation Research                      |  |  |  |
|                            |                                   | <ul> <li>Translational Research Center for TBI and Stress Disorders</li> </ul>      |  |  |  |
|                            |                                   | Quality Enhancement Research Initiative (QUERI) for Team-Based<br>Behavioral Health |  |  |  |
| Bronx, N.Y.                | James J. Peters VA medical center | National Center for the Medical Consequences of Spinal Cord Injury                  |  |  |  |
| Seattle, Wash.             | Seattle VA medical center         | Center for Limb Loss and Mobility   |  |  |  |
|                            |                                   | Center of Innovation for Veteran-Centered and Value-Driven Care                     |  |  |  |
|                            |                                   | <ul> <li>Improving Safety and Quality QUERI program</li> </ul>                      |  |  |  |
|                            |                                   | Suicide Prevention QUERI Partnered Evaluation                                       |  |  |  |
|                            |                                   | <ul> <li>Virtual Specialty Care QUERI program</li> </ul>                            |  |  |  |

Source: GAO summary of VA information. | GAO-20-211

Note: The Office of Research and Development's QUERI program works to translate research findings and evidence-based treatments into clinical practice.

### Appendix II: Information on Department of Veterans Affairs' (VA) Intramural Research Program Funding Levels for Awards

In fiscal year 2018, VA's appropriation for its intramural research program totaled \$722 million. Of this amount, \$558 million was for awards made by the Office of Research and Development's (ORD) four research services and the Cooperative Studies Program.<sup>1</sup> Table 3 below presents data on VA's intramural research program funding and awards for fiscal year 2018.

#### Table 3: Department of Veterans Affairs' (VA) Intramural Research Awards and Funding, Fiscal Year 2018

|  | Number of research awards      |                        |                                 |                 |  |
|--|--------------------------------|------------------------|---------------------------------|-----------------|--|
| Office of Research and<br>Development (ORD)<br>Component | Merit review and pilot studies | Cooperative<br>studies | Career<br>development<br>awards | Other<br>awards | Intramural award funding<br>(dollars in thousands) |
| Biomedical Laboratory Research & Development Service     | 750                            | 0                      | 51                              | 2               | \$184,311  |
| Clinical Science Research &<br>Development Service       | 238                            | 0                      | 56                              | 2               | 62,039   |
| Health Services Research &<br>Development Service        | 296                            | 0                      | 60                              | 20              | 105,473  |
| Rehabilitation Research &<br>Development Service         | 322                            | 0                      | 81                              | 20              | 111,507  |
| Cooperative Studies Program                              | 0                              | 45                     | 0                               | 0               | 94,684   |

Source: Data from VA. | GAO-20-211

Notes: In addition to the intramural award funding of \$558 million for the four research services and the Cooperative Studies Program in this table, VA's appropriation included \$164 million in fiscal year 2018 for other costs such as central office administrative support.

Merit review and pilot studies are administered by ORD's four research services; merit review studies are typically approved for four years, while pilot studies are approved for shorter time periods. Cooperative studies are administered by the Cooperative Studies Program, and are larger-scale, multi-site clinical trials or epidemiological research studies. Career development awards provide funding to support, train and mentor individuals early in their career as VA researchers, and can include funding for specific research projects. Other awards include, among other things, funding for the Million Veteran Program, which provides the infrastructure for enrolling at least 1 million veterans to create a research database of genetic, health, lifestyle, and military exposure information; human subject protection; and information technology.

<sup>&</sup>lt;sup>1</sup>The remaining amount of the appropriation—\$164 million in fiscal year 2018—was for costs such as central office administrative support.

# Appendix III: GAO Contact and Staff Acknowledgments

| GAO Contact              | Jessica Farb, (202) 512-7114 or farbj@gao.gov  |
|--------------------------|--|
| Staff<br>Acknowledgments | In addition to the contact named above, Raymond Sendejas (Assistant Director), Julie T. Stewart (Analyst-in-Charge), Lauren Anderson, Jennie F. Apter, Robin Burke, and Taylor German made key contributions to this report. Also contributing were Jacquelyn Hamilton and Vikki Porter. |

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